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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,576	04/16/2001	Elaine L. Jacobson	NIAD-213.1	6712

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EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/836,576	Applicant(s) Jacobson et al.
Examiner Sandra Saucier	Art Unit 1651

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on May 20, 2003
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6 and 8-12 is/are pending in the application.
- 4a) Of the above, claim(s) 11 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-6, 8-10, and 12 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 4) Interview Summary (PTO-413) Paper No(s). _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

Art Unit: 1651

DETAILED ACTION

Claims 1-6, 8-12 are pending. Claims 1-6, 8-10 and 12 are considered on the merits. Claim 11 is withdrawn from consideration as being drawn to a non-elected invention.

Election/Restriction

This application contains claim 11 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

Claims 1-6, 8-10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Insertion of the negative proviso "wherein said substance is not aminoguanidine" has no support in the as-filed specification. The insertion of this limitation is a new concept because it does not have any support in the as-filed specification by way of generic disclosure which would show possession of the concept of the exclusion of aminoguanidine as a substance to be screened in the claimed assay method. This is a matter of written description, not a question of what one of skill in the art would or would not have known. The material within the four corners of the as-filed specification must lead to the generic concept. If it does not, the material is new matter.

The issue at hand is whether the screening method as originally disclosed and claimed was originally contemplated to exclude aminoguanidine as a "substance". It is the examiner's position that the originally disclosed and claimed screening method was open to the screening of all "substances", and the exclusion of aminoguanidine as a "substance" in a negative proviso in response to the presentation of a reference showing a comparison of a control mixture and a mixture containing aminoguanidine which is demonstrated to be an inhibitor of fluorescence of histone-1 and ADP-ribose, is the insertion of new matter because it is a new concept.

The exclusion of certain "substances" implies the permissible inclusion of all other "substances" not so expressly excluded. This clearly illustrates that such negative limitations do, in fact, introduce new concepts.

Art Unit: 1651

INDEFINITE

Claims 5, 7 and 12 remain/are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 5, 7 and 12 it is unclear what bearing the measurements performed have on the determination of a substance which regulates glycation. The method is missing the relationship between the measurements. The parameters of the screening assay are still not clear. From reading the experimental section, it appears that the screening method is a complex one where positive and negative controls are employed in a screening process schematically disclosed in the flow chart in Figures 2 and 10. However, the claimed method does not make the sequence of comparisons which appear to be novel subject matter and the results thereof, clear. Careful reference to the scheme in Figures 2 and 10 and incorporation of these elements, instead of negative provisos, might advance prosecution to an allowance.

Claim 12 recites in line 5, "comparing the levels of fluorescence", however of what the fluorescence is has not been stipulated? There appears to be more than one type of fluorescence being measured.

Claims 1–4, 8, 9 are no longer rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cervantes-Laurean *et al.* [IDS] because of the insertion of new matter.

Applicant is hereby notified that the insertion of new matter into the claims has necessitated the removal of the art rejection above. However, removal of new matter may result in the reinstatement of the art rejection.

The original claims are directed to a method of determining if a substance regulates glycation comprising:

admixing (1) a substance to be tested, (2) ADP-ribose, (3) histone H1;
determining if the substance has an effect on glycation.

The reference is relied upon as explained below.

Cervantes-Laurean *et al.* discloses a method of admixing ADP-ribose and

Art Unit: 1651

histone H1 and measuring glycation. The reference also demonstrates that admixture of aminoguanidine to the system of ADP-ribose and histone H1 inhibits the crosslinking of H1. Measurement is by SDS-PAGE and by fluorescence (page 10466, second column). Incubation was for 20 minutes.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
July 28, 2003